



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3344]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information associated with adverse event reporting and recordkeeping for dietary supplements as required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2018-N-3344 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of

information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the
Dietary Supplement and Nonprescription Drug Consumer Protection Act

OMB Control Number 0910-0635--Extension

The DSNDCPA (Pub. L. 109-462) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to serious adverse event reporting and recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application. Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa-1) requires the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States to submit to us all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (Form FDA 3500A) when submitting a serious adverse event report to FDA. In addition, section 761(c)(2) of

the FD&C Act requires the submitter of the serious adverse event report (referred to in the statute as the “responsible person”) to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

Section 761(e)(1) of the FD&C Act requires that responsible persons maintain records related to the dietary supplement adverse event reports they receive, whether or not the adverse event is serious, for a period of 6 years.

As required by the DSNDCPA, we issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. The guidance entitled “Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act” is available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm>. It discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides our recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

The guidance recommends that the responsible person document their attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) communications between the responsible person and the initial reporter of the adverse event and between the responsible person and any other person(s) who provided information about the adverse event; (2) the responsible person’s serious adverse event report to us with attachments; (3) any new information about the adverse event received by the responsible person; and (4) any reports to us of new information related to the serious adverse event report.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

| 21 U.S.C. Section | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|--|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| 21 U.S.C. 379aa-1(b)(1)--serious adverse event reports for dietary supplements | 230 | 12 | 2,760 | 2 | 5,520 |
| 21 U.S.C. 379aa-1(c)(2)--followup reports of new medical information | 58 | 12 | 696 | 1 | 696 |
| Total | | | | | 6,216 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an annual decrease of 219 hours for reporting. We attribute this adjustment to a decrease in the number of reports we received over the last few years.

This estimate is based on our experience with similar adverse event reporting programs and the number of serious adverse event reports and followup reports received in the past 3 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting.

In the past 3 years, we received an average of 2,760 initial serious adverse event reports. We also estimated an average number of firms filing reports to be 230. Finally, we estimate that it will take respondents an average of 2 hours per report to collect information about a serious adverse event associated with a dietary supplement and report the information to us on Form FDA 3500A. Thus, the estimated burden associated with submitting initial dietary supplement serious adverse event reports is 5,520 hours (2,760 responses \times 2 hours) as shown in row 1 of table 1.

If a respondent that has submitted a serious adverse event report receives new information related to the serious adverse event within 1 year of submitting the initial report, the

respondent must provide the new information to us in a followup report. We estimate that around 25 percent of serious adverse event reports related to dietary supplements will have a followup report submitted, resulting in approximately 696 followup reports submitted annually. Dividing the annual number of reports among the 230 firms reporting results in approximately 12 reports for 58 respondents. We estimate that each followup report will require an hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the guidance. Thus, the estimated burden for followup reports of new information is 696 hours (696 responses \times 1 hour) as shown in row 2 of table 1.

Table 2.--Estimated Annual Recordkeeping Burden¹

| 21 U.S.C. section | No. of Recordkeepers | No. of Records per Recordkeeper | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
|--|----------------------|---------------------------------|----------------------|----------------------------------|-------------|
| 21 U.S.C. 379aa-1(e)(1)--dietary supplement adverse events records | 1,815 | 72 | 130,680 | 0.5 (30 minutes) | 65,340 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an annual increase of 2,440 hours for recordkeeping. We attribute this adjustment to an increase in the number of reports we received over the last few years.

All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event recordkeeping. We estimate that there are 1,815 such respondents. Estimating that each recordkeeper will keep approximately 72 records per year results in an annual burden of 130,680 records. Estimating that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hour, per record, results in an annual burden of 65,340 hours (130,680 records \times 0.5 hour).

Once the documents pertaining to an adverse event report have been assembled and filed in accordance with the safety reporting portal, we expect the records retention burden to be

minimal, as we believe most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20766 Filed: 9/24/2018 8:45 am; Publication Date: 9/25/2018]